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510 (k) Summary

Statement of Safety and Effectiveness

Kerr Advanced Adhesive

Kerr Advanced Adhesive is an all purpose dental adhesive consisting of a visible light curable methacrylate resin based mixture of monomers capable of forming both chemical and mechanical adhesive bonds to both natural tooth structures (enamel and dentin) and to commonly used restorative materials (composite resins, porcelain and metals). It is supplied as a one bottle, single step dental adhesive that is simple to use and produces fast, strong adhesion suitable for all commonly used restorative techniques. The organic solvent component allows the application of the adhesive to flow into micro-fissures of the substrate smoothly and when the fast evaporating solvent is removed a thin resin layer remains to form a tight bonding interface between tooth and restorative material.

The safety of Kerr Advanced Adhesive has been demonstrated by subjecting cured samples of the adhesive to various types of biocompatibility tests as recommended in the ISO 10993 biocompatibility guidance standard. These tests were conducted by an independent laboratory which specializes in safety and toxicity evaluation. The tests include:

1. Ames Mutagenicity Assay
2. Kligman Maximization Study (Allergic Potential Evaluation)
3. Cytotoxicity Study (MEM Elution Method USP 23)
4. Implantation Test (Tissue Sensitization)

Effectiveness or suitability to the intended purpose of **Kerr Advanced Adhesive** has been demonstrated by a combination of in-house testing and side by side test comparisons to a predicate device currently on the market. Results of this bench testing indicates that **Kerr Advanced Adhesive** performs as well or better than **PRIME & BOND, One-Step, and Tenure QUIK**, three predicate devices currently on the market and being represented as one step all-purpose dental adhesives